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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/693,121

Applicant(s)

SCHLOM ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-29 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20, 22 and 24-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The Office action mailed on 3/13/02 (paper no.7) has been vacated. Upon further reconsideration, the office will examine claims 17-20, 22, and 24-29 referring to cytokines and costimulatory molecules. Claims 21 and 23 drawn to orthopox and suipox are withdrawn from consideration since they are drawn to distinct species as set forth on page 4 item 4 of the office action mailed 12/18/01. Claim 22 will be examined to the extent that it reads on avipox, which includes, foxl pow, canary pox, pigeon pox. In addition RIBI will be examined.

### **SUPPLEMENTAL DETAILED ACTION**

1. The Office action mailed 3/13/02 (paper no 7) has been vacated, a new office action is newly set forth.

#### ***Election/Restrictions***

2. Applicant's election without traverse of group II (claims 4-10) in Paper No. 6 is acknowledged. Furthermore, applicant elects avipox/canary pox and RIBI Detox as the adjuvant. Upon further review, fowl pox and pigeon pox will be included in the group of avipox, therefore canary pox, fowl pox and pigeon pox will be examined.
3. Claims 1-16 have been canceled without prejudice and claims 17-29 have been newly added and are pending. Claims 21 and 23 are withdrawn from consideration as being drawn to a non-elected invention and claim 20 is examined to the extent that it reads on avipox. Therefore, claims 17-20, 22, and 24-29 are examined on the merits.

#### ***Claim Objections***

4. Claim 18 is objected to because of the following informalities: in line one of the claim, there is an extra "at". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17-20,22,24-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Regarding claim 17, in the recitation of the phrases: "*sufficient amount of PSA*", it is not known what the applicant intends as an amount that is sufficient for the generation of an immune response; "*effective amount of cytokine or co-stimulatory molecule*", it is not clear as to the amount that the applicant contends to be an effective amount. Clarification is required.
8. Regarding claim 18 and 19 in the recitation of the phrase "*additional PSA*", it is unclear as to the amount of PSA that is added during one of the periodic intervals of contacting the host with PSA; in the recitation of the phrase "*one periodic interval*", it is indefinite because the time period to which applicant refers is unclear and open and thus the metes and bounds of the term cannot be determined.
9. Regarding claims 17-20,22,and 24-29 in the recitation of the phrase "*T-cell eliciting epitope thereof*", it is indefinite because prostate specific antigen (PSA) has many potential epitopes that can elicit a T-cell response, therefore, the metes and bounds of the phrase cannot be accurately determined.
10. Claim 29 recites the limitation "pox vector" in claim 18. There is insufficient antecedent basis for this limitation in the claim.

### ***Double Patenting***

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 17-20,22,24-25 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 4-6,8, and 11-13 of prior U.S. Patent No. 6165460. This is a double patenting rejection.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 17 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bronte *et al* (J. Immunol 1995 May 15; 154(10):5282-92). Claims 17 and 26 are drawn to a method of generating an immune response to PSA by contacting a host with PSA and a cytokine or co-stimulatory molecule, wherein the cytokine is selected from group consisting of IL-2, IL-6, or IL-12.

Bronte *et al* teach a method of generating an immune response in mice to PSA by administering a peptide of PSA and a IL-2 cytokine.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



16. Claims 17-20,22,24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Correale *et al* (J. Immunol 1998 Sep 15; 161(6):3186-94) in view of Bronte *et al*. Claims 17-20, 22, 24, and 25 are drawn to a method of generating an immune response to PSA by contacting a host with PSA and a cytokine or co-stimulatory molecule, wherein the cytokine is selected from IL-2, IL-6, or IL-12, and further comprising contacting the host with additional PSA, wherein the additional contacting is accomplished by the introduction of an avi-pox virus, wherein the avi pow virus is selected from fowlpox, canary pox, and pigeon pox, and wherein the PSA is formulated with adjuvants.

Correale *et al* teach a method of generating an immune response to PSA by administering to a host PSA that is either in peptide form or is transferred by a vaccinia avipox viral vector, more specifically a vector under the control of the fowl pox C1 promoter (see in light of Hodge *et al Int J Cancer* 1995 Oct 9;63(2):231-7). Correale *et al* also teach the administration of the PSA peptide with a Detox adjuvant. However, Correale *et al* does not teach the combination of PSA and a cytokine.

Bronte *et al* teach the administration of a PSA molecule and a cytokine, specifically IL-2, and the improved effects of IL-2 administration with PSA.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate an immune response to PSA by administering PSA to a host in combination with a cytokine, wherein the PSA is administered in a viral vector with additional administrations of PSA to the host, because Correale *et al* has already taught that an immune response to PSA can be generated either through a peptide

followed by subsequent administrations of PSA by a viral vector. One would have been motivated to combine the references because Bronte *et al* specifically states that the administration of cytokines with PSA enhances immune response to PSA. One of ordinary skill would have expected a reasonable amount of success because the generation of an immune response to PSA was already proven to be possible, and Bronte *et al* indicates that the addition of cytokine only enhances the immune generating ability of PSA.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



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Christopher Yaen  
Art Unit 1642  
October 1, 2002

  
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